

Food and Drug Administration Rockville MD 20857

FILE COPY

December 03, 1999

Bert W. Rein Wiley, Rein & Felding 1776 K Street NW Washington, DC 20006

Dear Mr. Rein:

Your petition submitted on behalf of the American Association of Physicians and Surgeons, the Competitive Enterprise Institute and Consumer Alert requesting the Food and Drug Administration to revoke 201.23 require pediatric studies labeling, was received by this office on 12/02/99. It was assigned docket number 99P-5215/CP 1 and it was filed on 12/02/99. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Jennie Butler

Dockets Management Branch